



**MAR 11 2008**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Epicor Medical, Inc.  
c/o Ms. Kathi Guerrant  
Vice President, Regulatory Affairs and Quality Assurance  
1635 Energy Park Drive  
St. Paul, MN 55108

Re: K040641  
Trade Name: Epicor Medical UltraCinch Tissue Ablation Device and Accessories  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II (two)  
Product Code: OCL, NTB  
Dated: March 09, 2004  
Received: March 10, 2004

Dear Ms. Guerrant:

This letter corrects our substantially equivalent letter of May 5, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

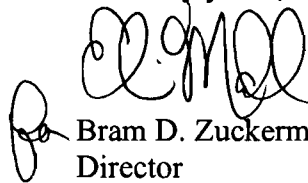
Page 2 - Ms. Kathi Guerrant

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'B. Zuckerman', is written over a circular stamp that is partially visible on the left.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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## Indications for Use

510(k) Number (if known): K040641

Device Name: **Epicor Medical UltraCinch Tissue Ablation Device and Accessory Pack**

Indications For Use:

The Epicor Medical UltraCinch is intended for the ablation of cardiac tissue during cardiac surgery.

The items in the UltraCinch Accessory Pack are intended for use in the ablation of cardiac tissue during cardiac surgery.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

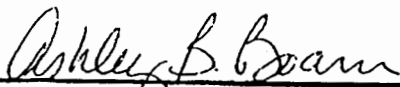
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K040641

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: \_\_\_\_\_

**MAY - 5 2004**

510(k) number: **K040641**

**Applicant Information:**

Epicor Medical, Inc.  
240 Santa Ana Court  
Sunnyvale, CA 94085-4512

**Contact Person**

Kathi M. Guerrant  
Phone Number: (408) 733-6500  
Fax Number: (408) 733-6682

**Device Information:**

Classification: Unclassified  
Trade Name: Epicor Medical UltraCinch Tissue Ablation Device and Accessories  
Classification Name: Ultrasonic Surgical Instruments

**Equivalent Device:**

The subject device is substantially equivalent in intended use and/or method of operation to the Epicor Medical UltraWand tissue ablation device (K022894), the Medtronic Cardioblate Radiofrequency Ablation System (K013392), the Boston Scientific Cobra RF and Cooled RF Family of Surgical Probes (K013873, K023291), the AFx Microwave Ablation System (K003978, K013946), and the CardioFocus Surgical Lightstic (K011988, K013901).

**Intended Use:**

The Epicor Medical UltraCinch is intended for the ablation of cardiac tissue during cardiac surgery.

The items in the UltraCinch Accessory Pack are intended for use in the ablation of cardiac tissue during cardiac surgery.

**Test Results:**

*Performance*

Results of *in vitro* testing, *in vivo* testing, and human clinical studies demonstrate that the Epicor Medical UltraCinch tissue ablation device and accessories are safe and effective for their intended use.

*Biocompatibility*

The materials used in the Epicor Medical UltraCinch tissue ablation device and accessories meet the requirements of ISO 10993-1.

**Summary:** Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.